

Routine Vaccine Management Plan

KEEP YOUR MANAGEMENT PLAN NEAR VACCINE STORAGE UNITS

The Tennessee Immunization Program (TIP) Vaccines for Children (VFC) Program requires VFC providers to maintain a vaccine management plan for routine **and** emergency situations. This template provides space for information about the practice, such as guidelines, protocols, contact information, and staff training. None of the information included in this template may be excluded in the plan.

Review and update your plan at least once a year, when VFC Program requirements change, and when staff with designated vaccine management responsibilities change. Key practice staff must sign and acknowledge the signature log annually and whenever any information on the plan is revised.

VFC Regional Immunization Representatives may ask to review your plans during routine and drop-in site visits.

STAFF ROLES AND CONTACT INFORMATION

Facility Name: _____

Facility Address: _____

Facility Phone Number: _____ **VFC PIN:** _____

Role/Responsibility	Name	Phone Number	Email Address
Provider of Record (Agreement signatory)			
Primary VFC Coordinator			
Back-up VFC Coordinator			
Immunization Champion (optional)			
Receives Vaccines			
Stores Vaccines			
Handles Shipping			
Other			

Please refer to [Page 3](#) of this document for descriptions of the key duties assigned to designated vaccine management staff.

Staff must sign and date the [Acknowledgement and Signature Log](#) at the end of this document to confirm that they understand and agree to the duties assigned to them.

VFC REQUIRED TRAINING LOG

Please list designated vaccine management personnel and have them sign and acknowledge that they have completed required annual training.

The Primary VFC Coordinator and Back-up VFC Coordinator must complete CDC's [You Call the Shots](#) Modules [10](#) & [16](#) for current year **OR** participate in a VFC Compliance Site Visit with their Regional Immunization Representative in the previous year **OR** participate in a VFC Education Visit with their Regional Immunization Representative in the previous year. TIP recommends that the Provider of Record, Provider of Record Designee, and additional staff at your facility also participate in these trainings in case of staff turnover.

Name and Title	Signature	Date Training Completed			
		Module 10	Module 16	Compliance Visit	Education Visit
Provider of Record (Agreement Signatory)					
Primary VFC Coordinator					
Back-up VFC Coordinator					
Provider of Record Designee					

KEY DUTIES FOR DESIGNATED VACCINE MANAGEMENT STAFF

TIP recommends that all staff who work with VFC vaccines are familiar with [VFC requirements and guidelines](#). Below are highlights of key duties for designated vaccine management staff.

Provider of Record:

- ☐ Complies with all federal vaccine management requirements, including key areas outlined in this plan
- ☐ Oversees designated vaccine management staff to ensure VFC program requirements are being met
- ☐ Completes recommended annual training, **at least one of the following:**
 - ☐ Complete CDC's [You Call the Shots](#) Modules [10](#) & [16](#) for current year
 - ☐ Participate in a VFC Compliance or Educational Visit in last year
 - ☐ Attend TIP VFC's Annual Review
- ☐ Designates one provider as Provider of Record Designee
- ☐ Designates one employee as Primary VFC Coordinator
- ☐ Designates one employee as Back-up VFC Coordinator
- ☐ Authorizes and reports changes to Primary and Back-up VFC Coordinators, Provider of Record, and Provider of Record Designee to the VFC Enrollment team at VFC.Enrollment@tn.gov or 800-404-3006 **within 10 business days** of changes being made
- ☐ Meets and documents required orientation and annual training for designated vaccine management staff
- ☐ Ensures designated vaccine management staff are skilled and knowledgeable regarding VFC requirements for temperature monitoring and storage equipment
- ☐ Ensures practice's vaccine inventory management is consistent with VFC program requirements
- ☐ Ensures practice's vaccine storage units and temperature monitoring devices meet VFC program requirements
- ☐ Updates and revises vaccine management plans at least annually and whenever necessary
- ☐ Reviews VFC program requirements and management plans with staff at least annually and whenever necessary

Primary VFC Coordinator:

- ☐ Completes required annual training, **at least one of the following:**
 - ☐ Complete CDC's [You Call the Shots](#) Modules [10](#) & [16](#) for current year
 - ☐ Participate in a VFC Compliance or Educational Visit in last year
 - ☐ Attend TIP VFC's Annual Review
- ☐ Meets all responsibilities described in [TIP VFC Provider Handbook](#) for VFC Coordinator

Back-up VFC Coordinator:

- ☐ Completes required annual training, **at least one of the following:**
 - ☐ Complete CDC's [You Call the Shots](#) Modules [10](#) & [16](#) for current year
 - ☐ Participate in a VFC Compliance or Educational Visit in last year
 - ☐ Attend TIP VFC's Annual Review
- ☐ Meets all responsibilities described for VFC Coordinator when Primary VFC Coordinator is not available

Provider of Record Designee:

- ☐ Completes recommended annual training, **at least one of the following:**
 - ☐ Complete CDC's [You Call the Shots](#) Modules [10](#) & [16](#) for current year
 - ☐ Participate in a VFC Compliance or Educational Visit in last year
 - ☐ Attend TIP VFC's Annual Review
- ☐ Meets all responsibilities for Provider of Record when Provider of Record is not available

The Primary VFC Coordinator should review and acknowledge the following requirements by checking the box next to each item:

VACCINE STORAGE EQUIPMENT

Equipment:

- ☐ This facility uses [VFC-compliant vaccine storage standalone refrigerator\(s\) and freezer\(s\)](#)
- ☐ Vaccine storage units maintain recommended unit temperature ranges:
 - Refrigerator: between 2 – 8 °C
 - Freezer: below -15 °C
- ☐ Vaccine storage units have adequate capacity to store vaccine supply at all times, including during peak back-to-school and flu season
- ☐ Vaccine storage units are routinely cleaned inside, kept dust-free outside, and have proper seals on the doors
- ☐ This facility keeps maintenance and repair records for vaccine storage units on file and makes them available to review upon request by TIP

Power Supply:

- ☐ Each vaccine storage unit is directly plugged into a wall outlet
- ☐ Each vaccine storage unit is not controlled by a light switch, power strips, or surge protectors with on/off switch
- ☐ Extension cords are never used to connect storage units to an outlet
- ☐ Plug guards are used to prevent power interruption
- ☐ "DO NOT UNPLUG" signs are posted at each outlet and at the circuit breakers

Set-up:

- ☐ Vaccine storage units are set up according to requirements outlined in the [TIP VFC Provider Handbook](#)
- ☐ Vaccine storage units are located away from direct sunlight and away from walls to allow air circulation
- ☐ Vaccines are never stored in the doors, drawers, or bins of storage units
- ☐ Drawers/deli crispers are removed from vaccine storage units
- ☐ Vaccines are stored 2-3 inches away from the walls, air vents, and floors of vaccine storage units to allow space for air circulation
- ☐ To stabilize temperatures, frozen cold packs are kept in freezers and water bottles are kept on the top shelf, in the door, and on bottom of refrigerators where vaccines cannot be stored.
- ☐ VFC and private vaccine storage areas/shelves are clearly separated and labeled to differentiate vaccine supplies
- ☐ Vaccines are organized in plastic mesh baskets and clearly labeled by type of vaccine
- ☐ Buffered temperature probes are placed in the center of the vaccine storage units, near the vaccines
- ☐ DDL displays are securely attached on the outside of vaccine storage units
- ☐ Vaccines are stored in their original packaging until administered
- ☐ Food, beverages, and laboratory specimens are never stored in vaccine storage units
- ☐ When medication or biologic media (not inoculated) are stored in the same unit as vaccines, they are placed on the shelves below vaccines

TEMPERATURE MONITORING EQUIPMENT

Digital Data Loggers (DDLs):

- ☐ Each vaccine storage unit has a continuous temperature monitoring device with the following capabilities:
 - ☐ Data that can be routinely downloaded

- ☐ Active display that is placed on the outside of the unit door to allow for reading temperatures without opening the unit door
- ☐ Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature
- ☐ Alarm for out-of-range temperatures
- ☐ Low battery indicator
- ☐ Accuracy of +/- 0.5°C
- ☐ Memory storage of at least 4,000 readings
- ☐ User-programmable logging interval (or reading rate)
- ☐ Detachable, buffered probe to help approximate the vaccine temperature rather than the air temperature
- ☐ Each DDL has a current and valid Certificate of Calibration (also known as a Report of Calibration Testing)
- ☐ Each DDL has a digital display of current, minimum, and maximum temperatures
- ☐ Each DDL displays temperatures in degrees Celsius (°C)
- ☐ Each DDL is set to alarm when:
 - Temperature in refrigerator goes **above** 8°C or **below** 2°C
 - Temperature in freezer goes **above** -15°C
- ☐ Probes are placed in the center of vaccine storage units and never in the unit doors, near or against the walls, underneath air vents, or on unit floors
- ☐ DDL batteries are replaced every six months
- ☐ There is at least one back-up DDL that is readily available on-site to ensure that temperature assessment and recordings can be performed twice a day

DDL Calibration:

- ☐ All primary and back-up DDLs are calibrated as recommended by the manufacturer
- ☐ DDL calibration is done by either a laboratory accredited by an ILAC MRA signatory body or an entity that provides documentation demonstrating that calibration testing meets ISO/IEC 17025 International standards for calibration testing and traceability
- ☐ Certificates of Calibration are maintained in a readily accessible area, until expiration, and presented to TIP staff for review upon request
- ☐ DDLs are replaced on or before expiration date listed on device
- ☐ DDLs are replaced when no longer accurate within +/- 0.5°C

Safeguarding Vaccines, Handling, and Reporting Temperature Excursions:

- ☐ When an out-of-range temperature is identified, immediate action is taken to assess the situation and to prevent vaccine spoilage
- ☐ Temperature excursions are reported immediately to 800-404-3006 or Temperature.Health@tn.gov
- ☐ Vaccines involved in temperature excursions are labeled "Do Not Use Until Further Notice"
- ☐ This facility has an Emergency Vaccine Management Plan to follow in case of power outage, appliance malfunction, severe weather conditions, or human error that may affect vaccine viability
- ☐ When necessary to transport vaccine to another storage unit or to a predetermined site, facility always follows CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid

Temperature Monitoring and Documentation:

- ☐ Vaccine storage unit temperatures are read twice a day, when the clinic opens and before it closes
 - ☐ Minimum and maximum temperatures are read and recorded once each day
 - ☐ AM temperatures are read and recorded before opening vaccine storage units

- ☐ PM temperatures are read and recorded at the end of each day, allowing time for corrective actions in the event of out-of-range unit temperatures
- ☐ [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are posted on storage unit doors or nearby
- ☐ [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are completed daily and DDL reports are printed weekly
- ☐ [Vaccine Storage Unit Digital Data Logger Sign-off Sheets](#) are initialed by person who documents temperatures
- ☐ Completed temperature logs are maintained for three years and made available to VFC Regional Immunization Representative upon request for review

Please refer to the [TIP website](#) for guidance on [Temperature Monitoring and Excursions](#)

INVENTORY MANAGEMENT

Inventory Maintenance:

- ☐ Physical vaccine inventory is [reconciled in TennIIS](#) at least once every 30 days and before ordering vaccines
- ☐ Enough vaccines are maintained in inventory to meet needs of VFC-eligible **and** VFC-ineligible patients
 - It is recommended to maintain a 4-week supply in case of unexpected delays in processing or delivery
- ☐ Facility has adopted an inventory control system
- ☐ Accurate records, including purchase invoices for privately purchased vaccines, are maintained and made available upon request to VFC Regional Immunization Representatives
- ☐ Vaccines that are drawn up and not used are disposed of correctly and recorded in TennIIS
- ☐ Facility stores diluent packaged with vaccine together
- ☐ Facility clearly labels diluents that are not packed with its vaccine so they can be easily identified
- ☐ Diluents are not placed in the freezer

Stock Rotation, Returns, and Transfers

- ☐ Vaccine stock is rotated monthly to assure that vaccines with the shortest expiration dates are used first
- ☐ If vaccine expires or spoils, it is:
 - Removed from storage unit
 - Reported to TIP VFC at VFC.Help@tn.gov
 - Returned to McKesson for excise tax credit within six months of expiration/spoilage
- ☐ If vaccine is due to expire within three months and will not be used, this facility will:
 - Notify TIP and Regional Immunization Representative about vaccine
 - Identify VFC providers in the area to contact and inquire if they may be able to use the vaccines
 - Request a transfer approval from TIP through TennIIS
- ☐ If facility needs to transfer or transport vaccine, CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid is followed
- ☐ Unused vials/syringes are returned to McKesson if unopened and in original packaging
- ☐ This facility does not return the following items:
 - Used syringes with or without needles
 - Syringes with vaccine drawn up and not used
 - Broken or damaged vaccine vials
 - Multi-dose vials that have already been withdrawn
- ☐ Spoiled, expired, or wasted vaccine are reported to TIP before placing a new vaccine order

Vaccine Ordering:

- ☐ Orders are submitted in TennIIS and placed according to clinic-based eligibility data, assigned order frequency, vaccine usage, and current inventory in stock
- ☐ When a vaccine is offered by two or more manufacturers, this facility orders one brand to mitigate administration errors
- ☐ A physical vaccine inventory is conducted before placing a vaccine order
- ☐ This facility places orders with sufficient inventory on hand to allow time for order processing delivery
- ☐ This facility confirms operation hours in TennIIS before submitting each order
- ☐ This facility reports any changes to the practice's hours to TIP to avoid receiving vaccine shipments when the clinic is closed or staff is not available

Receiving and Inspecting Vaccine Shipments:

- ☐ Staff is familiar with procedures for accepting vaccine shipments described in the [TIP VFC Provider Handbook](#)
- ☐ Vaccine shipments are inspected immediately upon arrival to verify that the temperature during transport was within range, and that the vaccines being delivered match those listed on the packing slip and order confirmation
- ☐ This facility assumes responsibility for all VFC vaccine that is shipped to its site
- ☐ This facility never rejects a vaccine shipment
- ☐ Shipment discrepancies and vaccines exposed to out-of-range temperatures are reported to TIP VFC Quality Assurance Team at 800-404-3006 or Temperature.Health@tn.gov immediately
- ☐ Vaccines are stored immediately upon delivery according to requirements described in the [TIP VFC Provider Handbook](#)
- ☐ Vaccines are accepted in the TennIIS inventory upon receipt

VACCINE STORAGE UNIT INFORMATION

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Refrigerator (3)				
Refrigerator (4)				
Freezer (1)				
Freezer (2)				
Freezer (3)				
Freezer (4)				

Where are your digital data logger reports and temperature logs located?

If you have a manual defrost freezer, please provide a description of your plan for regular defrosting:

DIGITAL DATA LOGGER AND CALIBRATION INFORMATION

Primary Data Loggers (must have one for each unit listed in previous section):

DDL Brand, Model #, Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting

Back-up Data Loggers (must have at least one readily available on-site):

Data Logger Model/Serial #	Calibration Date	Calibration Expiration Date	Low Alarm Setting	High Alarm Setting

Calibration Company: _____ **Phone Number:** _____

Location of Certificates of Calibration: _____

Location of Back-up DDLs: _____

USEFUL EMERGENCY NUMBERS

Service	Name	Main Phone Number	Alternate Number	Email Address
Utility Company				
Building Maintenance				
Building Alarm Company				
Refrigerator/Freezer Alarm Company				
Refrigerator/Freezer Repair Company				
Point of Contact for Vaccine Transport				
Regional Immunization Representative				
TIP VFC Quality Assurance Team * (available Monday – Friday, 8AM – 4:30PM)		(800) 404-3006	(615) 741-7247	Temperature.Health@tn.gov
VOMS * (available Monday – Friday, 8AM – 4:30PM)		(615) 404-3006		TennIIS.VOMS@tn.gov
VFC Help * (available Monday – Friday, 8AM – 4:30PM)		(800) 404-3006		VFC.Help@tn.gov
VFC Enrollment * (available Monday – Friday, 8AM – 4:30PM)		(800) 404-3006	(615) 741-7247 (fax)	VFC.Enrollment@tn.gov
TennIIS Help Desk * (available Monday – Friday, 7AM – 6PM)		(844) 206-9927		TennIIS.Help@tn.gov

*** Unavailable on all Tennessee State Holidays**

Emergency Vaccine Management Plan

The following sections include space for information and necessary actions to take in the event of an emergency, such as unit malfunction, mechanical failure, power outage, natural disaster, or human error.

In an emergency, contact the following people in the order listed:

Role/Responsibility	Name	Phone Number	Email Address
1.			
2.			
3.			
4.			

Does the clinic have a generator? If so, where is it located?

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If your clinic does not have a generator, and/or your vaccine storage unit fails, it may be necessary to transport vaccine to alternate storage locations.* Please identify two back-up locations:

Alternate Vaccine Storage Location	Address and City	Point of Contact Name	POC Contact Information
1.			
2.			

*** Alternate storage locations must have standalone vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements in the [VFC Provider Handbook](#)**

Where is the location of your emergency packing supplies?

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OTHER USEFUL EMERGENCY INFORMATION

Complete the following information for emergency storage units that will be used by your facility for emergencies that do not require an alternate storage location.*

Unit Type	Unit Location	Brand	Model Number	Serial Number
Refrigerator (1)				
Refrigerator (2)				
Freezer (1)				
Freezer (2)				

*** Alternate storage locations must have standalone vaccine storage units and continuous temperature monitoring equipment that is in compliance with requirements in the [VFC Provider Handbook](#)**

Use the following guidance for safeguarding vaccines in the event of planned or unplanned power interruptions (e.g. power outages, severe weather, building maintenance/repairs, etc.):

Before an Emergency:

- ☐ Maintain emergency contact information for designated vaccine management personnel
- ☐ Place water bottles on the top shelf, in the door, and on the bottom of vaccine refrigerators, where vaccines cannot be stored to stabilize temperatures. Place frozen cold packs in the freezers for similar purposes.
- ☐ Identify alternate vaccine storage locations (e.g. a local hospital, a local health department, or another VFC provider). Ensure the location has adequate space to accommodate vaccines and that their temperature monitoring equipment meets [VFC program requirements](#).
- ☐ Update necessary contact information for alternate vaccine storage locations, including facility name, address, contact person, and telephone number.
- ☐ Stock emergency supplies as indicated in CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
- ☐ Label and keep accessible any necessary vaccine packing and transport supplies, copies of vaccine transport job aids, facility floor plans when available, and other related information
- ☐ Be familiar with back-up power sources for commercial, laboratory, and pharmacy-grade storage units

During an Emergency:

- ☐ Assess the situation. Do not open the vaccine storage unit.
- ☐ Determine the cause of the power failure and estimate the time it will take to restore power.
- ☐ Notify key vaccine management staff listed on the Emergency Plan as appropriate
- ☐ If the power outage is expected to be short-term, usually restored within 4 hours:
 - ☐ Record the time that the outage started, unit temperatures (current, minimum, and maximum) for each day, and the room temperature
 - ☐ Place a "DO NOT OPEN" sign on the storage unit(s) to conserve cold air mass
 - ☐ Monitor the temperature until power is restored
- ☐ If the outage is expected to be long-term, usually longer than 4 hours, consider moving vaccines to an alternative unit or facility. See details below, under Relocating Vaccine.

NOTE: Temperatures in vaccine storage units tend to increase faster during power outages. As a result, clinics may need to monitor temperature more frequently and/or transport vaccines to an alternate location sooner.

Relocating Vaccine:

If a power outage is expected to be long-term (e.g. not restored within four hours) or storage units are not working properly, prepare to relocate vaccines to alternate storage locations.

Before transporting vaccines:

- ☐ Review CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
- ☐ Contact the alternate storage facility to verify that they can accept the vaccines
- ☐ If transport or relocation is not feasible (e.g. alternate location is not available or travel conditions are unsafe):
 - ☐ Keep units closed and document the current, minimum, and maximum temperatures for each day
- ☐ Notify the TIP VFC Quality Assurance Team at 800-404-3006 or Temperature.Health@tn.gov

Packaging and transporting vaccines:

- ☐ Complete the [Refrigerated Vaccine Transport Log](#) and/or the [Freezer Vaccine Transport Log](#)
- ☐ Prepare cooler(s) for transport following CDC's [Packing Vaccines for Transport during Emergencies](#) Job Aid
 - ☐ Use frozen cold packs for frozen vaccines. Never use dry ice.
 - ☐ Use conditioned (slightly defrosted) frozen packs for refrigerated vaccines. Placing refrigerated vaccine directly on frozen packs and packaging it without sufficient insulation may freeze and therefore, damage vaccine. If clinic does not have time to condition frozen packs, refrigerated cold packs or cold water bottles may be used.
- ☐ Package and prepare diluent
 - ☐ Diluent for MMR, varicella, and MMRV can be stored at room temperature or in the refrigerator
 - ☐ Diluents stored in the refrigerator should be transported with refrigerated vaccines
 - ☐ Diluents stored at room temperature should be transported at room temperature
 - ☐ Diluents packaged with their vaccine should be transported with their vaccine
- ☐ Upon arrival at the alternate vaccine storage location, document total vaccine transport time, the current, minimum, and maximum temperatures in the transport cooler(s), and the current, minimum, and maximum temperatures in the alternate storage unit(s).

After Power is Restored:

- ☐ Verify storage units are functioning properly and temperatures are within range before attempting to move any vaccine
- ☐ Follow the same transportation procedures and transfer vaccine back to its original storage unit
- ☐ Vaccine kept at the proper temperature during the power outage, whether transported or not, may be used
- ☐ For any vaccine not stored at proper temperature:
 - ☐ Segregate it in the storage unit
 - ☐ Mark it "Do Not Use Until Further Notice"
 - ☐ Contact the TIP VFC Quality Assurance Team at 800-404-3006 to report the excursion
- ☐ Never return vaccine to the vaccine distributor without authorization from TIP

Acknowledgement and Signature Log

Please sign and date this acknowledgement and signature log when you update practice-specific information each year during annual re-enrollment.

By signing this log, facility staff are acknowledging that they have reviewed, understand, and agree to the key duties assigned to them as vaccine management personnel for this facility.

Updates and comments to changes made in Routine and Emergency Vaccine Management Plans:

PROVIDER OF RECORD:

Name: _____

Signature: _____ Date: _____

PRIMARY VFC COORDINATOR:

Name: _____

Signature: _____ Date: _____

BACK-UP VFC COORDINATOR:

Name: _____

Signature: _____ Date: _____

PROVIDER OF RECORD DESIGNEE:

Name: _____

Signature: _____ Date: _____

ADDITIONAL STAFF (optional):

Name: _____

Signature: _____ Date: _____

Name: _____

Signature: _____ Date: _____